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filing option during any of the few telephone conversations held a few days prior to the first final rejection deadline. The other options suggested by the Examiner were to either file an appeal or pay for extensions of time. The latter would have kept mounting each month and would not lead anywhere, as any amendments to the claims were not entered on the grounds that they would necessitate a new search, which made it extremely difficult if not virtually impossible to bring the claims into condition for allowance. The appeal option was considered but shelved because of the Examiner's offer to bring the application into allowance on what turned out to be unaceptable but hopefully negotiable terms, as discussed under the following point.

Re Points 5 and 59: Applicant appreciates the Examiner's attempt "to further the instant application to an Allowance" and especially the Examiner's having "painstakingly drafted a set of....claims" that might have been allowable. However, that set of claims included a restriction that would have made it easy for anyone to freely appropriate the main features of the patent with the exclusion of that restriction, which would have rendered the issued patent worthless. Moreover, in the last telephone conversation, the Examiner indicated that even with that restriction the claims may still be objectionable in view of the Hardt patent that turned up in a more recent search. However, it is believed that the below-presented replies will overcome the cited objections and lead to allowance of the claims without need for any further amendments. If the Examiner's attempt "to further the instant application to an Allowance" was really bona fide, then a withdrawal of the altogether unjustified final rejection may be called for. The assertion under Point 59 that our "amendment necessitated the new ground(s) of rejection" raises the following questions:

i. Considering that the Claim Rejections under Points 24-58 are substantially the same as those of the preceding Office Action of 6/26/2009 (Points 12-34), as brought out in our replies below, what "new ground(s) of rejection" was (or were) necessitated by our amendment?

ii. Does an additional argument under Point 39 in support of a previous rejection constitute "new ground(s) of rejection," and why was that argument necessitated by our moving the words "from a volume of air" in claim 12 from one part of a sentence to the beginning of the same sentence?

It is therefore respectfully requested that the unjustified final rejection be withdrawn so as to allow time for, and otherwise permit, any further amendments that would fully satisfy the Examiner.

Re Points 7-9 and 20-23: These are interpreted as an indication that the terminal disclaimer, as drafted, will be acceptable upon payment of a $65.—disclaimer fee, which is appreciated. However,

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absent an indication of the allowability, conditional on that payment, of any of the claims that may be subject to a double-patenting objection (claims 1-15 and 19), any payment for a terminal disclaimer may be premature at this time and may constitute an unjustified waste of money should none of these claims be eventually allowed. It is therefore proposed to hold the fee payment in abeyance pending an indication of the conditional allowability of at least some of the subject claims.

Re Examiner's Points 10 and 11:

The following three judicial decisions are cited by the Examiner in support of the view that "intended use has been continuously held not to be germane to determining the patentability of the **apparatus**:"

i. In re Finsterwalder, 168 U.S.P.Q. 530;

ii. In re Hirao, 190 USPQ 15; and

iii. Kropa v. Robie, 88 USPQ 478.

The last of these decisions appears to be the most pertinent one to our case, as we find nothing relevant in Finsterwalder, and **the Hirao decision deals with "process steps" and not with apparatus** and rejects a "Solicitor's interpretation of the preamble" that "would improperly broaden the scope of the claim," i.e., the opposite of our preamble, which highly restricts the scope of our claims.

More relevant to our claims are the underlined and highlighted sentences in the following paragraph from Kropa v. Robie, 187 F. 2d 150, 152, 88 USPQ 478, 481 (CCPA 1951):

"**[**6]** This court has often had before it the Jepson problem (243 O.G. 525--1917)-- **[*152]** whether the preamble to claims in ex parte cases or to the counts in interference cases should be considered as limitations in the claims or counts. Of the thirty-seven cases of this court we have reviewed with respect to this problem it appears that the preamble has been denied the effect of a limitation where the claim or count was drawn to a structure and the portion of the claim following the preamble was a self-contained description of the structure not depending for completeness upon the introductory clause; or where the claim or count was drawn to a product and the introductory clause merely recited a property **[***481]** inherent in the old composition defined by the remaining part of the claim. In those cases, the claim or count apart from the introductory clause completely defined the subject matter, and the preamble merely stated a purpose or intended use of that subject matter. On the other hand, **in those ex parte and interference cases <u>where the preamble to the claim or count was expressly or</u>**

by necessary implication given the effect of a limitation, the introductory phrase was deemed essential [7] to point out the invention defined by the claim or count. In the latter class of cases, the preamble was considered necessary to give life, meaning, and vitality to the claims or counts. Usually, in those cases, there inhered in the article specified in the preamble a problem which transcended that before prior artisans and the solution of which was not conceived by or known to them. The nature of the problem characterized the elements comprising the article, and recited in the body of the claim or count following the introductory clause, so as to distinguish the claim or count over the prior art.**"

It is respectfully submitted that the instant claims are addressed not at a modern art structure that may be composed of disjoint elements serving no declared purpose, but rather at a **novel means, whether apparatus or method, for ultra-sensitive detection of hazardous airborne constituents based on wet electrostatic precipitation, as fully and aptly characterized by the underlined and highlighted sentences from Kropa v. Robie.** The following excerpts from the amendment dated April 24, 2009, which may not have been entered, point out the distinctions of our claims from the vast amount of electrostatic-precipitation-based prior art that was directed at clean-up of air but not at detection of its hazardous constituents. **It is therefore respectfully urged that all the rejections dismissing our preambles as irrelevant be reconsidered in view of the above-highlighted sentences from Kropa v. Robie.**

That our claims are directed not at the prior art of electrostatic precipitation but rather at the art of air contaminants collection and detection is brought out in the following slightly edited excerpt from Page 6 of our Amendment dated April 24, 2009:

"Although the experimental work of Example 1 of the specification, Paragraphs 0044-0054, had to be confined to 1 micron particles with our available instrumentation, the following excerpts from the specification emphasize the applicability of our invention to much smaller particles:

Paragraph 0008: "According to the latter references, **wet EP can achieve collection efficiencies of 99.9% for particles as small as 0.01 micron in size** and for various gaseous species, including dioxins/furans, **which could also assure capture of toxins and dry virus particles. The latter remain suspended in air long after evaporation of water from the droplets in which they were originally dispersed and may thus present a persistent not**

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readily noticeable hazard. Therefore, an ability to collect dry virus particles should greatly enhance the effectiveness of biological agent detection systems. "

Paragraph 0056: "The high airflow rates and collection efficiencies which are achievable with wet EP technology not only for particles 1-10 microns in size but also for submicron particles render the PHTLAAS-EP applicable to ultra-sensitive detection of not only cellular pathogens, such as anthrax or tuberculosis bacilli, but also of the much smaller toxins and dry virus particles. The latter may pose a serious hazard following vaporization of the droplets in which they were originally dispersed. The capability to collect toxins and dry virus particles will therefore greatly strengthen the arsenal for defense against biological warfare agents".

The ability of our wet EP instrument to efficiently collect submicron-size virus particles... is evidenced by a pioneering paper of Zaromb et al., in the **Proceedings of the 2007 SCIENTIFIC CONFERENCE ON OBSCURATION AND AEROSOL RESEARCH,** Battelle Eastern Science and Technology Center, Aberdeen, MD, 20 June 2007. For the Examiner's convenience, this paper is appended herewith following the end of our present reply.

Although electrostatic precipitators have been known to collect particles as small as 0.01 micron, their potential importance in the collection and detection of virus and toxin particles has not been previously appreciated," which adds to the novelty and patentability of our claims.

Re Examiner's Points 12-19:

Re Point 12: The Examiner's wording "capable of performing this function" raises the following questions. What function can the cited devices perform and in what manner? Would that function be compatible with the disclosures of the cited patents and do these patents call for its performance? Since the cited Grindell patent operates as a dry device, how would it be capable of smoke detection if its inner surface were wetted? If the inner surface of Bentley's electrostatic precipitator were fully wetted, how effectively would it substantially remove "droplets of mist remaining in the gas stream" [Column 3, Lines 33-35]?

Re Point 13: Bentley's "means for introducing an analyte-free collection liquid" is shown in their Fig. 2, **which uses baffled separators but does not include any electrostatic precipitator**, and at the entrance 26 to the baffled separators of Fig. 3 which are separated from the electrostatic precipitator by several components of the system. **The electrostatic precipitator of Fig. 3 is not exposed to any "analyte-free collection liquid" but rather to a mist generated from a "partially contaminated" liquid [Column 3, Lines 39-47].**

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Re Point 14: Bentley's Item 3 of Fig. 3 forms part of their baffled separators section which is separated from the electrostatic precipitator by several components of their system. **Since the precipitator is not "forming part of said chamber," as required by our basic claim 1, Item 3 does not relate in any way to our claims.**

Re Points 15-19: Bentley's **Item 17 is shown in their Fig. 2 as leading to an analyzer** and in their Fig. 3 as "DIRTY LIQUID" 57 feeding to "LIQUID CLEANING AND RECOVERY" 60. **There is no mention of an analyzer in conjunction with Fig. 3 and no mention of electrostatic precipitation relating to Fig. 2.** Since Fig. 2 utilizes solely baffled separators, its analyzer 23 does not pertain to the collection and detection of hazardous particles via wet electrostatic precipitation. Even in their Fig. 3, their invention is not based on electrostatic precipitation but on baffled separation, and elimination of their featured electrostatic precipitator could only allow some of their final mist droplets to escape with their exhaust without otherwise affecting the operation of their system. Therefore Bentley's "intended use and method of use," as quoted from Column 1, Lines 23-36, and "the analysis and detection," as quoted from Column 1, Lines 3-16, refer to their invention based on baffled separators and not on electrical precipitation.

Re Examiner's Points 24-32:

These points are duplicates of Points 11-19 from the Office Action of 6/26/2009. These have been replied to in our last amendment, dated August 30, 2009, pages 5-8, which are incorporated herein by reference. In view of those replies, it is surprising that the Examiner keeps asserting in his Point 27 that "Bentley discloses in a **wet electrostatic precipitation-based** apparatus" most of the features of our basic claims, **in spite of the clear disclosures in Bentley's Columns 1-3 and Figs. 1 and 3 that their invention and apparatus are based on their use of baffled separators** and where their only mention of an electrostatic precipitator is for an appendage intended to remove residual mist droplets from the final stage of their clean-up application.

Moreover, since all of these points lead up to the assertion of Point 32 that it would have been obvious "to modify the wet electrostatic precipitation based apparatus of Bentley et al with the substantially vertical electrostatic precipitator and collector tubes of Grindell and/or Hardt et al," the following questions arise:

A. Aside of the erroneous misnomer – "wet electrostatic precipitation based" in lieu of "baffled separators based" – where in Bentley's Fig. 1 or 3 would the Examiner propose

insertion of "substantially vertical electrostatic precipitator and collector tubes" so as to in any way resemble our claims?

B. How would that affect the functioning and performances of the system of Fig. 1 or 3 or of the inserted tubes?

C. How would such insertion into a baffled separator system be relevant to the true electrostatic precipitation-based apparatus and methods of our claims?

Re Examiner's Points 33-38:

These points are duplicates of Points 20-25 from the Office Action of 6/26/2009. These have been replied to in our last amendment, dated August 30, 2009, pages 8-9, which are incorporated herein by reference.

Re Examiner's Points 39 and 40:

These points are substantially the same as the part of Point 20 pertaining to Claims 12-14 on Page 6 of the Office Action of 6/26/2009 to which a few sentences have been added pertaining to the obviousness of collecting a sample "from a specific volume of air." Since this issue is not disputed, it may suffice to copy here the following answers to the objections of 6/26/2009 that were submitted on Pages 8-9 of our last amendment, dated August 30, 2009:

"Re Claims 12-14 (Page 8): As pointed out above, Bentley's Figs. 1 and 2 are not relevant to any detection apparatus or method because they don't deal with electrostatic precipitation but solely with "baffled separators;" and the incidental precipitator of their Fig. 3 is related to removal of droplets but not to any detection method. Grindell's invention involves "ascertaining the smoke content in a flow of gaseous fluid" by measuring "the total electric charge of the particles which strike" an "electrode per time unit" (Column 1, Lines 56-63). His disclosure does not include any "capturing for detection" of "aerosolized particles as small as 0.01 micron in size "as specified in our Claim 12. Therefore, neither of these references can provide a basis for a 35 USC § 103 rejection.

Moreover, as to the objection to **Claims 12-14**, we not only find no mention of "an electrostatic precipitation-based aerosol collector" in Bentley's Summary of Invention or Column 1, Lines 23-36 or Column 2, Lines 10-17, but the "piezoelectric ultrasonic transducer" found in these citations serves to generate mist particles but not to capture them. However, claim 12 has been further amended to start with the wording "A method of capturing for detection..." which again excludes from consideration the electrostatic precipitator of

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Bentley's patent. Objections based on the argument that electrostatic precipitators capture sub-micron-size particles would be valid for applications pertaining to air scrubbing, such as those of Bentley's Fig. 3, but not to capture for detection, which is a new application of such precipitators. It is to be noted that most existing aerosol collectors intended for monitoring of hazardous air contaminants can not capture sub-micron-size particles with the efficiency that is required for their ultra-sensitive detection. Any virus particles that they collect are mostly those which are attached to larger carriers, such as water droplets or dust particles, or are agglomerated into larger sizes. Since individual virus particles or their smaller agglomerates remain afloat in air for longer times and in larger numbers than the larger carriers or agglomerates, their efficient collection greatly enhances their detection sensitivity and thus opens the way to timely detection of hazardous viruses, such as those of pandemic influenza. The realization of the importance of such new detection capability constitutes a novel discovery which should qualify for patent protection."

Re Examiner's Points 41-49:

These points are duplicates of Points 26-34 from the Office Action of 6/26/2009. These have been replied to in our last amendment, dated August 30, 2009, pages 9-10, which are incorporated herein by reference.

It is therefore respectfully requested that the final rejection be withdrawn and our claims found to be allowable conditionally on payment of the terminal amendment fee.

Respectfully submitted by,

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From **Proceedings of the 2007 Scientific Conference on Obscuration and Aerosol Research**, Battelle Eastern Science and Technology Center, Aberdeen, MD, 20 June 2007.

COLLECTION, DETECTION, AND IDENTIFICATION OF AEROSOLIZED SUBMICRON-SIZE VIRUS PARTICLES

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Present collection of aerosolized pathogens excludes particles of <1 micron. Because most single toxin or virus particles are smaller than 1 micron, their collection must be restricted to larger aggregates or to particles carried by dust or droplets. Once these settle out, break up or dry up, the remaining floating smaller aggregates or single virus or toxin particles are overlooked with present collectors.

A recently developed device based on wet electrostatic precipitation, WEP, collects 1-micron fluorescent beads at efficiencies of >80% and an air flow rate of 500 liters/minute. To test its applicability to submicron-size particles, a WEP instrument collected aerosolized and dried dilute suspensions of MS-2 phage. Tests of the collection liquid for MS-2 with the Army's Integrated Virus Detection System yielded efficiencies ranging from >15% to >90%.

Introduction

Present Defense Department requirements for bio-aerosol collectors exclude particles smaller than 1 micron, which includes most or all single toxin or virus particles whose collection must then be restricted to larger aggregates or to particles carried by dust or droplets. Once these settle out, break up or dry up, the remaining floating smaller aggregates or single virus or toxin particles, which must make up the vast majority of such hazardous constituents, are overlooked with present collectors.

Earlier beliefs that single virus particles can not be easily aerosolized and are not retained in the respiratory tract are contradicted by recent demonstrations that:

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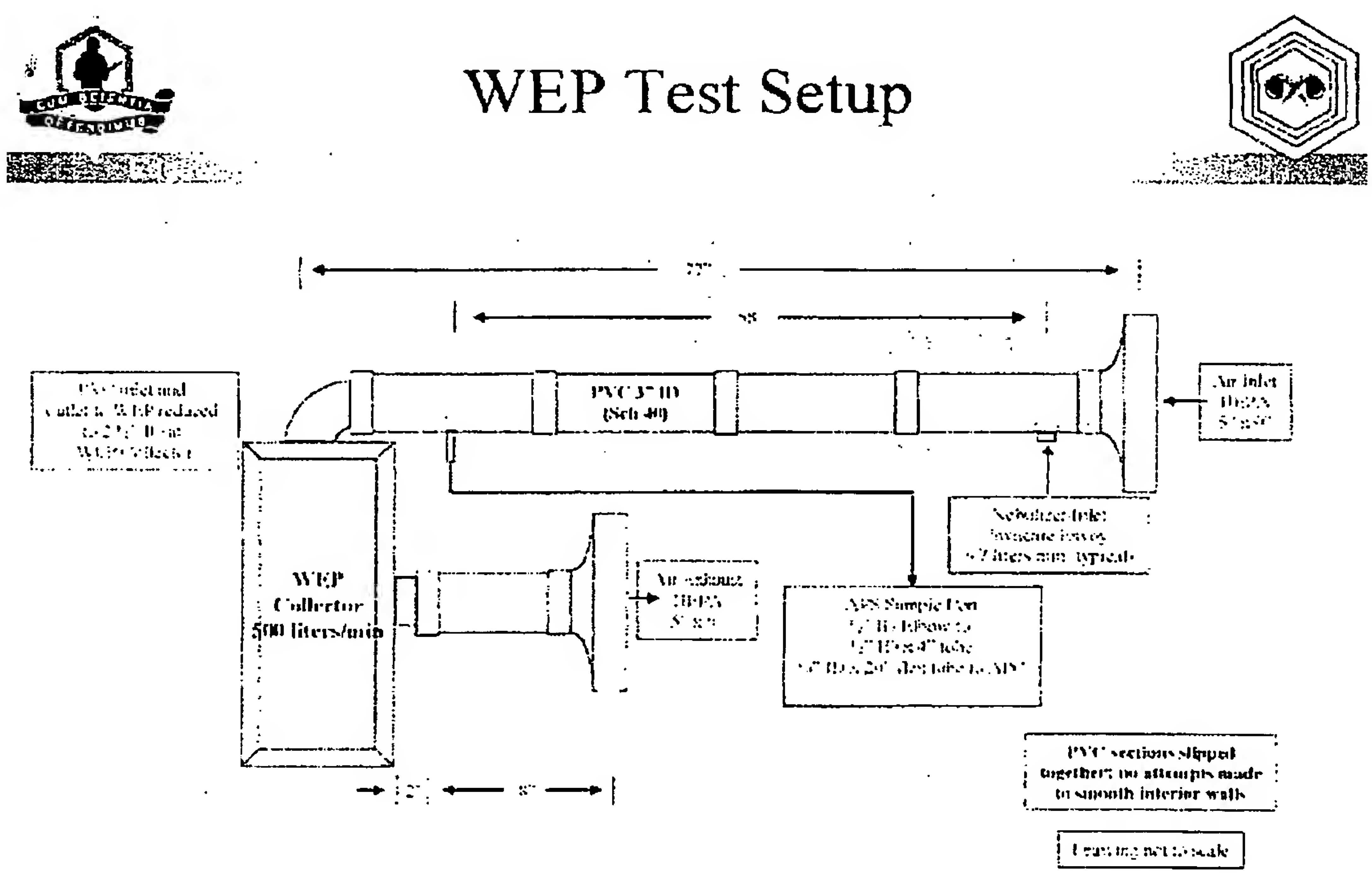
- Submicron viral aerosols can be created, albeit in small quantities thus far;[i]
- Submicron particles do get deposited in the lungs;[ii] and
- Their efficiency of capture by the lungs depends on their size, but the 100-nm particles have a capture efficiency of ~20%.[ii]

Smaller particles are thought to penetrate deeper in the lung where they can rapidly enter the blood stream.[2]

Therefore, the absence of efficient collectors for submicron particles may constitute a serious vulnerability to both viral attacks by enemy agents and to naturally generated viral aerosols.

Electrostatic precipitation-based devices have been known to capture particles ranging in size from <0.1 micron to >10 microns at efficiencies of >90%. A collector based on wet electrostatic precipitation [WEP], recently developed under an Army-sponsored SBIR project, collects 1-micron fluorescent beads at efficiencies of >80% and an air flow rate of 500 liters/minute.[iii] To test its ability to collect single virus particles, we used the setup of Fig 1 to aerosolize and dry dilute suspensions of an MS-2 phage and collect the aerosol with a WEP instrument.

Fig. 1



To verify that most of the droplets generated by the nebulizer have evaporated before reaching the WEP collector, we nebulized 5 ml of distilled water over a 5-minute period and sampled the air at the nebulizer outlet and WEP intake at half-minute intervals with an Aerodynamic Particle Sizer [APS]. The results are summarized in Figs. 2 and 3, which show that >98% of droplets ≥1 micron vanish before reaching the collector.

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Fig. 2

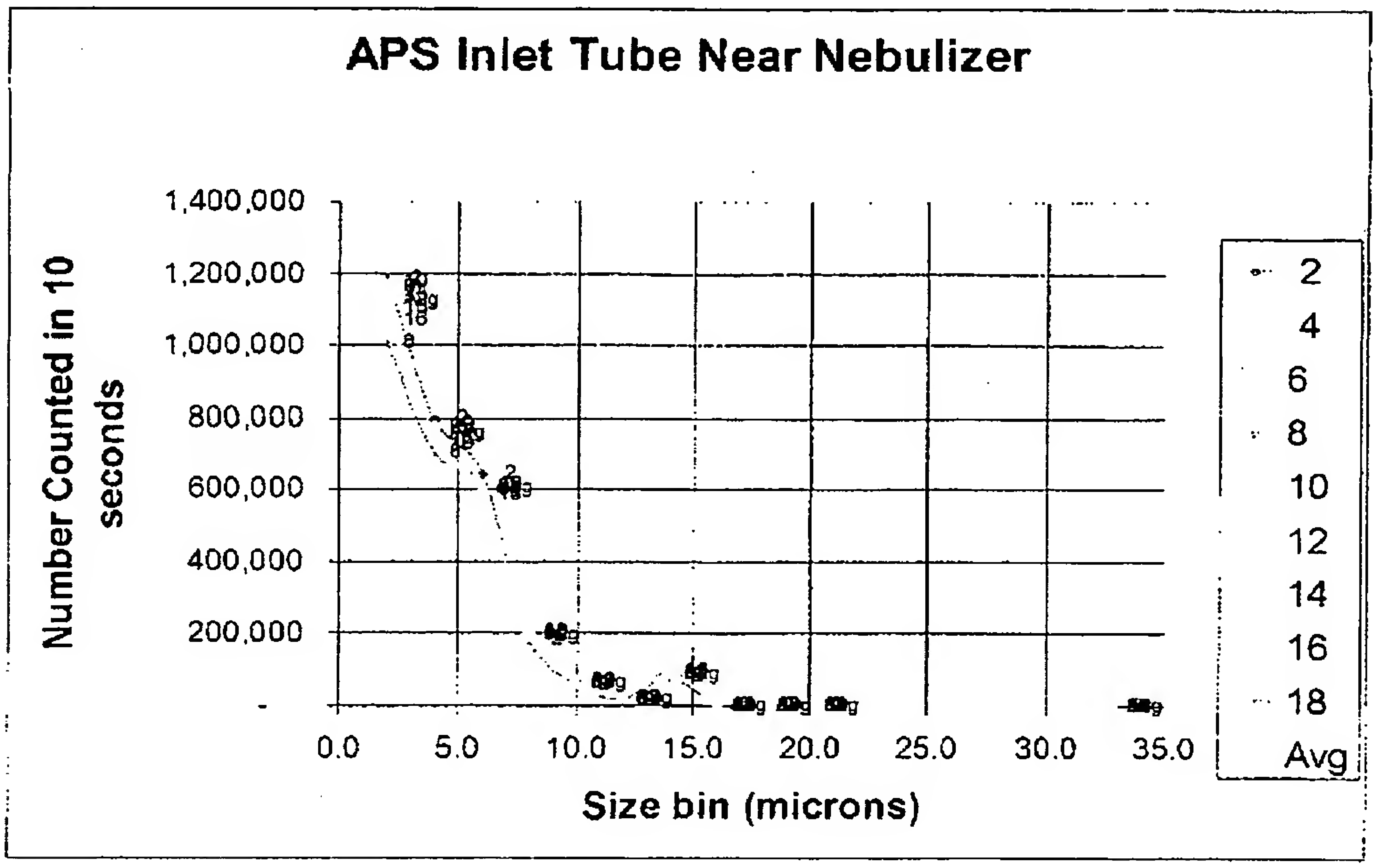
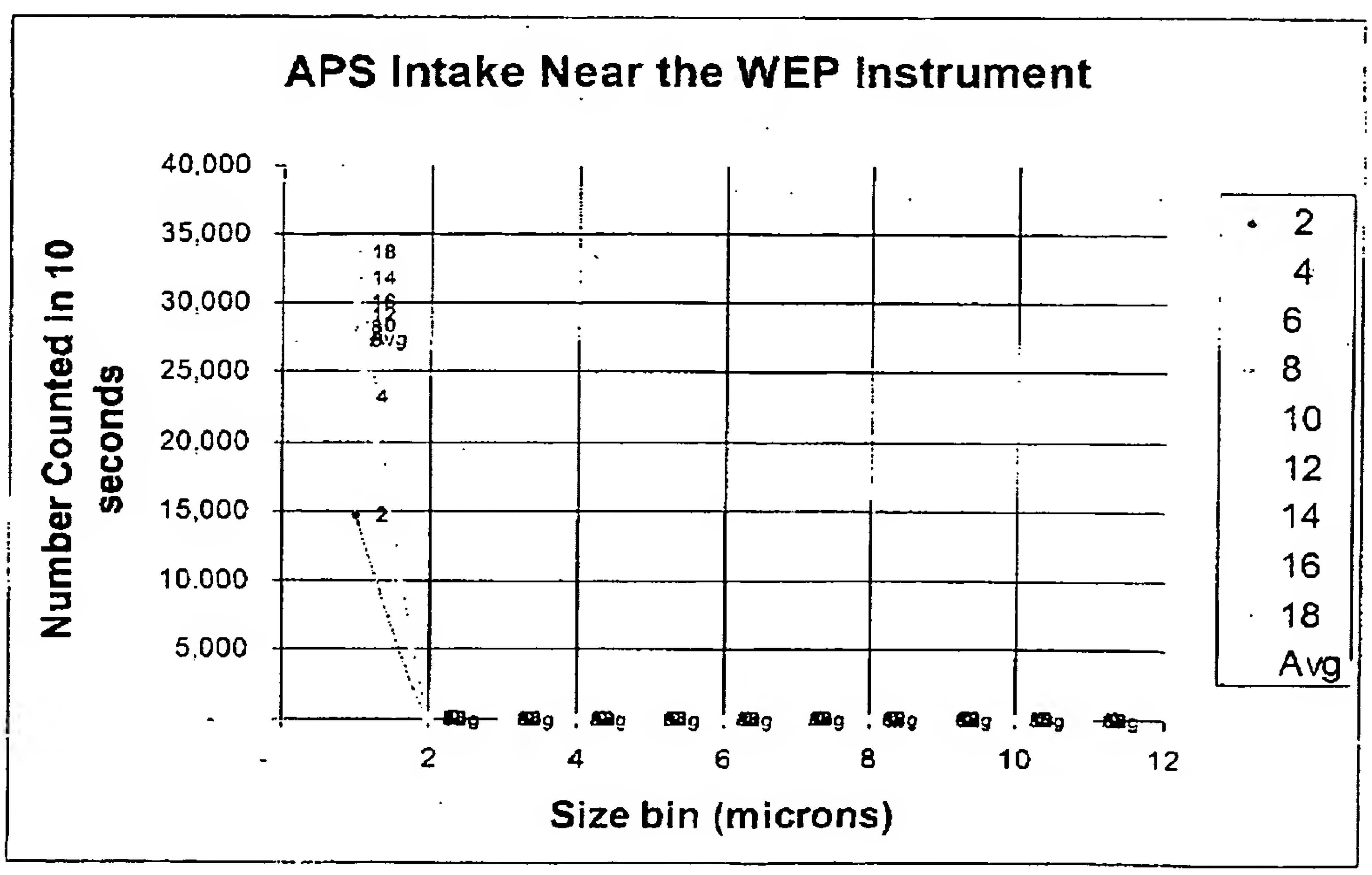


Fig. 3



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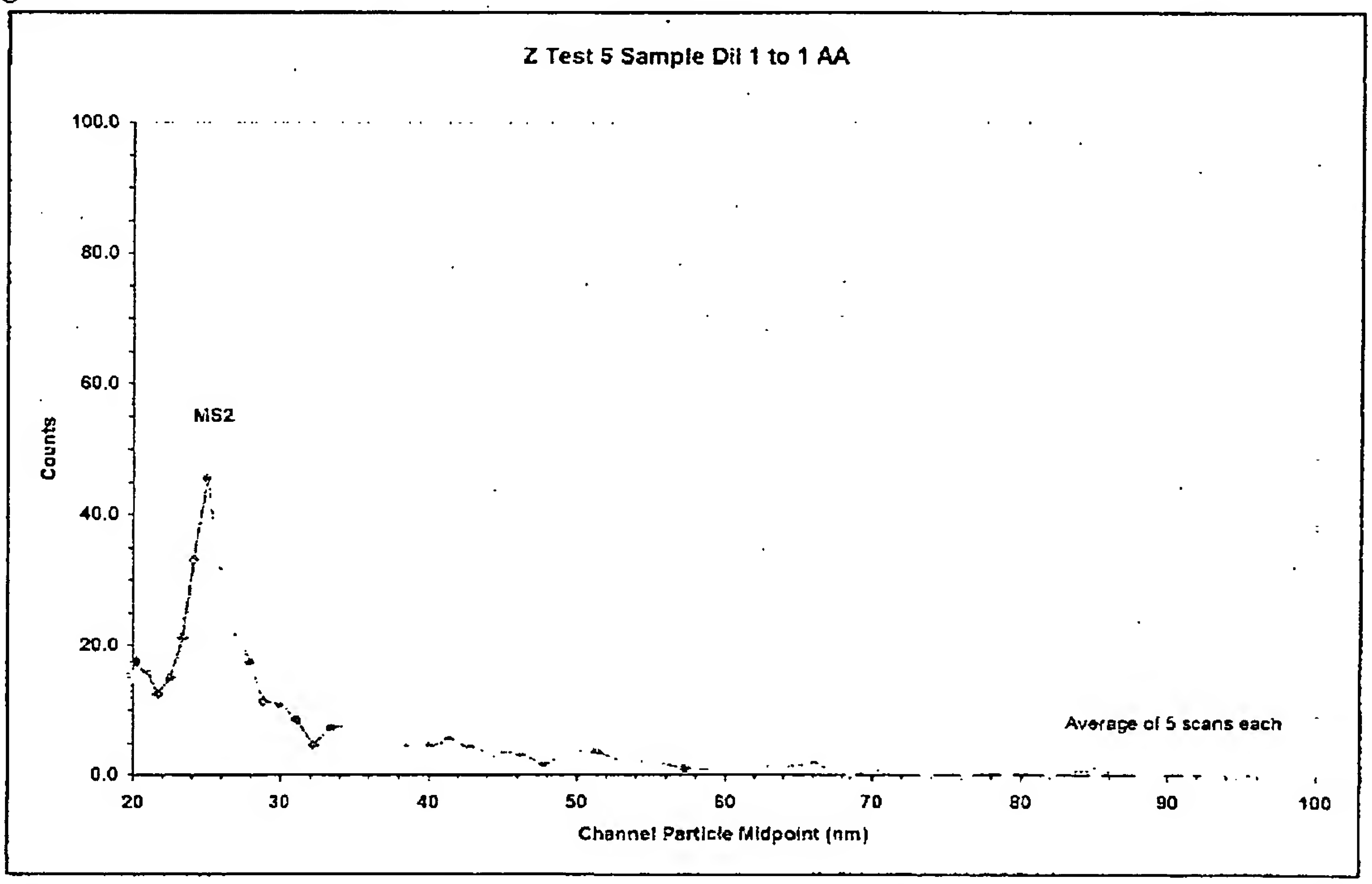
The few 1-micron particles shown in Fig. 3 may have been either residual droplets or solid residues from not perfectly pure water, which may explain the observed increases in the numbers of these particles as the nebulizer content was going down from 5 ml to 1.4 ml.

Test Results

The collection efficiency for MS-2 was then tested with an Integrated Virus Detection System (IVDS) comprising a virus particle imager and counter developed at the US Army's Edgewood Chemical Biological Center.[iv]

The first test yielded a count of 1,000 particles 24.1 nanometers in size in a 50-nanoliter sample, corresponding to a collection efficiency of >15%. Subsequent tests yielded efficiencies ranging from ≈30% to >90%. The full data for the last of these tests are presented as follows:

Fig. 4



IVDS analysis of Test 5 sample after dilution of 1:1 with 20 mM ammonium acetate -- MS2 detected

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Assumption: time progresses linear with channel midpoint				
Capillary flow 80 nl/min (previous capillary flow analysis, Aug 2004)				
80 nl/60 s = 1.3 nl/s				
and 120 channels in 60 s = 0.5 s/channel				
4 s x 1.3 nl/s = 5.2 nl				
ROI counts 97/5.2E-6 ml = 1.9E7/ml				
Concentration factor of 2 = 3.8E7/ml				

IVDS analysis of stock sample = ~2×10^9 counts/ml
Volume dispersed: 5 ml
Collection Time: 8:08 minutes
Sample collected: 60 ml

Collection Efficiency ≈
80 ml x 3.8×10^7 (counts/ml)/[5 ml x 2 x 10^9 counts/ml] ≈ 30%

Average phage concentration in sampled air ≈
5 ml x 2 x 10^9 counts/ml/[8.1 min x 500 L//min] ≈ 2.5 x 10^6 counts/L

Conclusions

The demonstrated detection sensitivity may be improved more than 100-fold by subjecting the collected liquid volume to centrifugation or ultra-filtration so as to reduce it to <1 ml.

Further tests are called for to evaluate possible applications in timely discovery of pandemic infections in work places, employee cafeterias, airplanes, cruise ships, and other frequented facilities or places.

Acknowledgement

Thanks are due to Mr. Bryan Christensen, of the Division of Environmental Health Engineering, Johns Hopkins University, Baltimore, MD 21205, for supplying the MS-2 phage samples used in the herein reported tests.

References

[i] B. Heimbuch, Personal Communication, August **2006.**
[ii] F. R. Casse et al., Arch. Toxicol. 76: 277-286, **2002.**
[iii] S. Zaromb, D. Martell, I.Ray, N. Schattke, and G. Hankins, "Electrostatic Precipitation-Based Aerosol Collector," **2006 SCIENTIFIC CONFERENCE ON OBSCURATION AND AEROSOL RESEARCH**, Battelle Eastern Science and Technology Center, Aberdeen, MD, 28-29 June **2006.**
[iv] Charles H. Wick, **"Analysis of the Physical Behavior of Viruses Using the Integrated Virus Detection System (IVDS)"**, Edgewood Chemical Biological Center **Report Number** A431334, Dec 2004.